SEP - 5 2003

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Name, Address, Phone and Fax number of the Applicant

Acueity, Inc.
100 Hamilton Avenue, Suite 140
Palo Alto, CA 93401

Telephone: (650) 473-9910
Fax: (650) 473-9306

B. Contact Person

Nancy Lincé
Regulatory Affairs Consultant
Telephone: (650) 759-6186

C. Date Prepared

July 15, 2003

D. Device Name

Trade Name: Medical Light Source
Classification Name: Endoscopic Accessories

E. Device Description

The Medical Light Source was specifically designed for medical applications. Therefore, the highest safety requirements for the patient as well as for the physician are applied. The Light Source combines highest illumination requirements with high-resolution video capabilities through an integrated high-resolution ¼", ½" or 1/3" CCD camera board.

F. Intended Use

The Acueity Medical Light Source is indicated for use in illuminating the operative site and providing video images that can be displayed on a monitor. The device

is designed for attachment to endoscopes and laparoscopes that are used in medical procedures.

G. Substantial Equivalence

The Acuiety Light Source and Video Camera System is substantially equivalent to the Welch Allyn Illumination Platform (K951647). The Medical Light Source is substantially equivalent to the predicate device in intended use, technological characteristics, materials, manufacturing processes, and components.

H. Device Testing Results and Conclusion

All necessary testing was performed on the Medical Light Source to ensure that the product is substantially equivalent to the predicate devices and to ensure that the device does not raise new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2003

Acueity, Inc.
c/o Ms. Michelle Weidman
KEMA Medical
4377 County Line Road
Chalfont, Pennsylvania 18914

Re: K032430
Trade/Device Name: Medical Light Source
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FCW
Dated: August 21, 2003
Received: August 22, 2003

Dear Ms. Weidman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K032430

Device Name: Medical Light Source

Indications For Use:

The Acueity Medical Light Source is indicated for use in illuminating the operative site and providing video images that can be displayed on a monitor. The device is designed for attachment to endoscopes and laparoscopes that are used in medical procedures.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032430

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)